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Radiation Experiments on Children at the Fernald and Wrentham Schools: Lessons for Protocols in Human Subject Research

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The Massachusetts Task Force on Human Subject Research has so far been the only serious attempt to investigate radiation experiments on humans. No other federal, state or private agency has looked at a specific experiment in detail. The President's Advisory Committee on Human Radiation Experiments (ACHRE) provided an overview of the entire nationwide research project, but without a thorough evaluation of any single experiment. The Massachusetts Task Force examined a group of experiments using institutionalized children at two state facilities, the Fernald and Wrentham schools, from 1943 to 1973. The experiments were performed under supervision by scientists at Harvard and MIT, and were funded by several federal agencies. The Task Force found that these experiments were conducted according to the ethical and protocol standard of their day. This did not prevent the Task Force from judging that the experiments violated human rights, and recommending apology and compensation to the victims.

Keywords: Radiation experiments; informed consent; ACHRE; bioethics; human experimentation; mental retardation, protocols

INTRODUCTION

In the spring of 1993, as a gesture of resolution to decades of cold war, President Clinton ordered federal agencies to release a massive amount of previously classified information. Among the documents made public, reporters discovered evidence of federally-funded radiation experiments performed on human beings without their knowledge or consent. The victims of these experiments included people considered marginal or unimportant by society at large: African Americans, low income women, "mentally retarded" children. This article is an effort to summarize the findings of one investigation into an experiment done during this time and to comment on current policies and laws protecting research participants.

Part 1 is a historical overview of the public release of the radiation documents, and of coverage of their importance in the news media. **Parts 2–4** give an account of one response to these events: the creation by the state of Massachusetts of a 'Task Force on Human Subject Research'. **Part 2** details the efforts of the Task Force as it further examined the contents and background of the identified studies. **Part 3** presents its findings, and **Part 4** explains its recommendations, discusses current bioethical issues in medical, social, and behavioral research—with a view to illustrating some of the issues that must be considered as we develop new standards for research in the 21st century.

PART 1: THE NATION AND MASSACHUSETTS ARE ALERTED TO EXPERIMENTS INVOLVING RADIOACTIVE MATERIALS AUTHORIZED BY THE UNITED STATES GOVERNMENT

In November 1993, the Albuquerque Tribune published a series of articles by Eileen Welsome describing research from the 1940s, where human subjects had been injected with plutonium. Many of the radiation experiments had been previously published in 'peer-read' medical literature, where it had escaped notice or criticism until the time of Welsome's article. Welsome's story identified many of the victims personally, which gave an emotional tone to the story—an essential factor in focusing national attention on any issue.

Coverage of Welsome's story soon spread to newspapers and television stations across the country, and the Boston Globe followed up with another surprising discovery: there were indications that children living at a state-administered school for the "mentally retarded", the Fernald school in Massachusetts, had been used as subjects in radioactive experiments conducted by Harvard and MIT researchers throughout the 1940s and 50s. (The story by Globe reporter Scott Allen, printed Dec. 26, 1993, was based on information provided by Sunny Marlowe, a former librarian at the Fernald school.)

As a response to this disclosure, Philip Campbell, Commissioner of the Department of Mental Retardation in Massachusetts, created the Task Force on Human Subject Research, and charged this Task Force with a path-breaking investigation of all human studies conducted in Massachusetts, both in state-administered facilities and in any hospitals conducting research that may have used residents from these facilities. The Task Force was composed of family members of the victims, advocates in the field of mental retardation, attorneys, clergy, educators, physicians, and two former Fernald students. A bioethicist, Doe West (the author of this article), was appointed to serve as project coordinator, primary researcher and author of the reports. MIT and Harvard faculty members were not named to the Task Force itself, but were invited to serve on an advisory committee along with a selection of state and national experts and advocates.

The federal agencies funding these experiments (the Atomic Energy Commission (AEC, later Department of Energy (DOE)), the U.S. Public Health Service, and the National Institute of Arthritis and Metabolic Diseases) had never, voluntarily or by any legal requirement, notified the public of what took place, either at the time, in subsequent years, or during the initial wave of disclosures in the press. They also had not informed the victims, either then or in later years, as these and other similar experiments were being disclosed and discussed. The DOE has been judged by the victim advocates and the public at large as particularly accountable, since it has historically been the agency people have turned to for this kind of information. When Congressman Edward Markey (Mass.) conducted an investigation specifically concerned with human radiation experiments, the DOE neglected to make any mention of the Fernald experiments, in spite of information available in its own files (Markey, 1994).

Another issue that deeply concerned the Task Force was whether or not the local educational institutions co-sponsoring and directing the experiments, including MIT and Harvard University had ever fully or accurately informed the victims or the victims' parents that radioactive materials were being used.

Questions of professional ethics, as well as more basic issues of human morality, loomed large in the minds of the Task Force members (see Part 3). The victims and their families remained ignorant of any danger until 40 to 50 years later, when the story made national headlines. By then, the lack of any protective guidelines concerning record keeping and storage by the experimenters had made some of the victims impossible to locate or even accurately identify.

The difficulties encountered during this investigation made two further points especially clear:

(1) Only the will and dedication of a few select individuals—in Massachusetts, reporters Welsome and Allen, librarian Marlowe, commissioner Campbell, and the Task Force members and its advisory members—brought about the disclosure of important facts to the public that had been in federal files and medical journals for 40–50 years without comment or notice.

(2) A wide variety of people served on the Task Force, from victims and their family members to attorneys and physicians. People affiliated with the institutions under investigation were not appointed to the Task Force, but acted as advisors instead. This division of power—keeping a wide cross- section of people in the investigative body, but delegating those with possible conflicts of interest to advisory roles—was instrumental to a fair and even-handed investigation.

PART 2: RESEARCH AND REPORTING OF THE TASK FORCE

Over the winter of 1994, members of the Task Force reviewed tens of thousands of archival records pertaining to the Fernald experiments in an effort to understand and detail the individual and institutional failures that had permitted these ethically questionable experiments to occur as well as to identify measures that might be needed to prevent such abuses from occurring again. The Task Force expected that their results would be of interest to the public at large and to the newly-formed President's Advisory Committee on Human Radiation Studies (ACHRE). They also anticipated that their final report would serve as a prototype for similar reviews across the United States, and hoped by including actual archival records (with identifying details removed to protect privacy), they could set an example of integrity and thoroughness that would carry over into other ethical investigations of science.

Due to an absence of centralized data and records, the investigation was circuitous, and sometimes dependent on luck. Archives at the Fernald School provided only limited information: a handful of permission letters and a few notations of unique blood tests. The pivotal documents were discovered by two chance findings.

The first of these was a set of uncatalogued boxes found in Harvard University archives, which had belonged to Dr. Clemens Benda, the Medical Director of Fernald at the time of the experiments. A second chance finding of additional Benda records was made after a last-minute trip to an estate sale at Benda's former home, where boxes marked "Fernald" had been seen in one of the basements. Within Benda's boxes were a set of monthly progress reports made by the doctoral student who conducted the actual experiments. The reports had been sent to the student's advisor at MIT, who then sent them on to Benda as a matter of professional courtesy. These reports contained data which enabled researchers to make up a full and verified set of names, dates, and dosages for all of the boys who were subjects in the Fernald calcium experiments.

The experiments that were originally reported in the media were nutritional studies conducted at Fernald by the Nutritional Biochemistry Laboratories at MIT. These studies involved radioactive calcium isotopes, and their goal was to explore the impact of phytates (a naturally occurring chemical in oats) on the body's assimilation of calcium. (The radioactive isotopes were used as tracers to follow the metabolism of calcium). These studies were authorized by the Atomic Energy Commission and funded by the Quaker Oat company. (Task Force, 1994)

However, during a routine literature search on the calcium studies, a series of journal articles were discovered which gave reference to another, earlier nutritional study at Fernald, this time involving the use of radioactive iron isotopes. The original doctoral dissertation documenting the iron studies was located at the MIT library. In contrast to the calcium dissertation, this dissertation identified subjects by name and gave dosage data for each subject within its original data section.

The literature search also revealed a third group of studies (involving four separate experiments between 1952 and 1961) conducted both at Fernald and at another state facility, the Wrentham School. These four studies were investigations of thyroid function in children with mental impairment. They differed significantly from the calcium and iron studies in the type of radioactive isotope used and in the purpose of one of the studies.[1] The isotope used in the thyroid studies, Iodine-131, is one of the most dangerous fission products of uranium (Shcherbak, 1996; Horn *et al.*, 1989; Kerber *et al.*, 1993). Of key concern was the finding that one of the thyroid studies conducted at Wrentham was conducted for cold war purposes, rather than for nutritional or medical research.

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[1] This discovery led to an extension of the Task Force's work for an additional three month timespan.

The cold war thyroid experiment at Wrentham was designed to investigate human uptake of radioactive iodine from the milk supply following a nuclear accident or attack. The experiment measured whether normal iodine added to the diet could block the uptake of radioactive iodine. The subjects were 70 children ranging in age from 1 to 11 years. They were given large doses of stable (nonradioactive) sodium iodide in quantities ranging from 100 to 1,000 micrograms daily for 12 weeks. Iodine-131 was used as a tracer to measure the uptake of the stable iodine. During this experiment, five two-year-old children were given one microcurie every two weeks for a duration of 14 weeks, for a total exposure of 8 microcuries. (Saxena *et al.*, 1962)

In this and all other experiments done at Wrentham, complete identification of the subjects has remained impossible. Even a second review of the Benda papers was of no benefit since he was not involved in this study. None of the surviving experimenters involved in the Wrentham study had kept their records, and an exhaustive review of available articles against census data created only a partial list of potential subject identities.

PART 3: FINDINGS OF THE TASK FORCE

One of the most surprising findings of the Task Force was that the Fernald and Wrentham studies *met or exceeded the standards of their day in terms of official authorization protocol and paperwork.* The researchers had applied for and received permission from the federal and state agencies that oversaw the facilities, funded the experiments, and authorized the use of radioactive materials. (Task Force, 1994; Perkins, 1946; Tadgell, 1949; Lough, 1949a; 1949b; 1949c). They had also received the permission of parents and/or administrators at the schools, who had legal guardianship of the students. They were well-documented, academically-supervised experiments, published in nationally recognized and respected journals which still exist (Fernald Records, 1953; Sharpe *et al.*, 1950; Bronner *et al.*, 1954; 1956a; 1956b; Saxena *et al.*, 1962; 1965; Benda *et al.*, 1954; Kurland *et al.*, 1957).

Nevertheless, Task Force members reacted in shock and anger when reviewing the records of these experiments. All members of the Task Force agreed that according to current conceptions, fundamental bioethical standards had been breached in these experiments. However, a significant number thought it important to acknowledge that this research pre-dated many of our current policies and laws. A majority vote affirmed that the human rights of the children had been violated and that an immediate apology, with any and all compensations suggested by the federal government's ACHRE study, should be made to the victims.

We had the excrutiating task of trying to retroactively assess not only the actions of the researchers, but also their intent or knowledge of wrongdoing. Had they, for instance, truly believed that they had obtained the valid consent of their research subjects? Had they omitted information concerning the use of radioactive isotopes in order to deliberately hide it, or was the omission an unconscious act reflecting the paternalistic attitude of physicians and the bittersweet relationship America had with radiation during that era? (Snider, 1957; Strauss, 1955; Heller, 1956) Had they deliberately chosen people with disabilities for dangerous research they would not have dared to perform on non-disabled people? These and a whole litany of similar questions called out for response. However, the focal question immediately became clear: did any *harm* come to the subjects as a result of this research?

Medical and Psychological Harm

In order to estimate what potential harm had been done to the subjects, the Task Force retained a set of outside experts in radiation, epidemiology and endocrinology. Following their review of the calcium, iron and thyroid studies the experts felt that none of the children had received a radiation dose strong enough to significantly increase the risk of adverse health effects.

Although this retrospective analysis determined that the risk of physical harm was minimal, it remains to be seen whether this is a reasonable health risk prediction over time. Many victim advocates believe that there is no such thing as a "safe level of exposure". America has had a very complex love/hate relationship with radiation. Throughout the 1940s and 50s, radiation was used fairly indiscriminately. In the Navy, for instance, radiation treatment was used as a treatment for sinus conditions in submariners (ACHRE 1995a, p. 352). In the public sector, doctors offered X-ray therapy for personal issues ranging from removal of birthmarks to serious disease. "The editor of the American X-ray Journal said that there are about 100 named diseases that yield favorably to X-ray treatment. Radiation treatment for benign diseases became a medical craze that lasted for 40 or more years. [...] Entrepreneurs and quacks also saw a special use for X-rays by women. All across the United States, beauty shops installed X-ray equipment to remove their customer's unwanted facial and body hair. The biggest operation was the Tricho Institute, founded by Albert Geyser, a New York physician. Geyser leased X-ray machines to beauty parlors and gave two-week courses to operators." (Caufield, 1989) Local shoe store owners also saw the opportunity to use this most modern of scientific wonders to help show exactly how well a pair of shoes fit children's feet. The author of this article personally had her feet X-rayed by a young clerk in a shoe store to assure a good fit! This occurred at the same time that American children hid under their desks during civil defense drills. (Schools, 1982)

Records indicate that as far as the Fernald and Wrentham researchers could reasonably anticipate, their experiments would cause no harm. A letter from the director of MIT's Nutritional Biochemistry Laboratories to the superintendent of Fernald guarantees the safety of the experiments: "The quantities which we would give emit less energy than from the cosmic rays continually bombarding people living at the altitude of Denver. [...] There is absolutely no ground for caution regarding the quantities of radioactive substances which we would use in our experiments" (Harris, 1945). Another letter from a physics professor at MIT to a doctor at the Atomic Energy Commission also states that the amount of radiation used in the calcium experiments would not cause any harm (Evans, 1949). On the basis of these two sources, it appears that the researchers operated under an assumption that the experiments would pose no physiological danger to the children.

With regard to psychological harm, the quality of everyday life at Fernald was already severely damaging (See "Quality of Life" section on p. 115). But in many ways, the most severe psychological harm directly associated with the experiments occurred as a result of the disclosure and investigations performed by the Task Force itself because it made it necessary for many of the victims to relive painful buried memories. For example, one of the victims had never told a single living person about his time at Fernald; now as a father and a trusted professional in his community, he had to risk considerable change in the manner in which society would perceive him as a result of his having a history of being a resident in such an institution. One of the victims' wives states the trauma of reliving his time at Fernald in front of the media had been so assaultive to her husband's psyche, that he began having nightmares, and lost trust in everyone associated with the institution and with the investigation as a whole. (Personal communications)

Another source of psychological harm to these men during the investigation and disclosure process was created by the tone and nature of the media presentation. "Mental retardation", "mongolism", "idiocy" and other demeaning terms had been used in medical literature at the time of the Fernald experiments, and it was impossible to prevent the media from using these labels again today. Beyond their demeaning nature, these terms were also grossly inaccurate when applied to Fernald residents, many of whom, since the founding of the school, had been institutionalized for reasons more properly classified as "sociocultural": disobedience to parents, restlessness or rebellion in school, etc. Repeated direct effort to relay this information to the media, so that the stigma of the term "mentally retarded" would not be used in connection with these men, proved futile. The shock value of headlines such as "Radiation Used on Retarded" (Boston Globe, December 26, 1993, p. A1) was too great to allow reality to diminish its effect. This was, and continues to be, a source of great pain and anger to the men who had the bravery and fortitude to come forward as spokespersons for their peers.

Ethical Codes and Moral Principles

When the Task Force members were first informed of the Fernald and Wrentham experiments, we were unanimously shocked and angry, even before beginning detailed investigation. Based on our current views, these experiments were unquestionably wrong. But, in judging decisions made forty to fifty years ago, we could not necessarily apply the standards of conduct we now consider ethical in total isolation. On the other hand, we could not ignore that traditional principles of moral behavior have existed for thousands of years, and form the basis for all laws and codes that are presently applied. We therefore distinguished three levels of authority over ethical decisions:

(1) Ancient principles and human rights
(2) Written laws, codes, or professional standards
(3) Policies, practices and protocols in effect at specific institutions

In assessing the ethics of the Fernald and Wrentham experiments, we looked at what written codes and professional standards required at the time, and we examined whether these standards were applied specifically in policy decisions either at those schools or at other comparable institutions. In cases where standards were violated, we asked whether this was done *knowingly*, i.e. whether the researchers were aware of existing standards, or had attempted to comply with them.

Among the ancient ethical principles relevant to American law, ACHRE defined six that apply to these experiments (and with which our discussions fully concur): "One ought not to treat people as mere means to the ends of others"; "One ought not to deceive others"; "One ought not to inflict harm or risk of harm"; "One ought to promote welfare and prevent harm"; "One ought to treat people fairly and with equal respect"; and "One ought to respect the self-determination of others". These are considered "immediately recognizable and widely accepted ethical principles that are not usually thought to require justification". (ACHRE, 1995a, p. 198, p. 222)

The most famous *written* code of human research ethics at the time of Wrentham and Fernald was the Nuremberg Code of 1947. This set of guidelines was codified during the Nuremberg Medical Trials, when a number of human rights violations of Nazi scientists came to light, including horrific experiments on human captives resulting in disability or death. Although the Nuremberg Code did not exist at the time of the actual Nazi war crimes, it was applied retroactively under the assumption that its guiding principles were recognized in the "natural law" of all people (ACHRE, 1995a, p. 103; Grodin, 1992). But the Task Force determined that it could not be held as the sole or official standard for judgment due to its lack of legal authority in American policy at that time. Physicians who had practiced during the 1950s argued before the Task Force that the Nuremberg Code was seen more as a statement of judgment against the atrocities committed by the Nazis, than as a valid code of research ethics and we had no documentation available to us to prove otherwise. (Needless to say, this was a point of active argument.)

Outside of the Nuremberg Code, legal research shows that American legislative bodies debated bills prohibiting experimentation without consent (particularly on children or handicapped adults) as far back as 1900. However, these bills did not become law, demonstrating that consent issues were still controversial and in process of being defined.

After the Task Force had written its final report and disbanded, new and deeply disturbing facts emerged from research done by the ACHRE Committee: letters and memos from federal regulatory agencies (including the Atomic Energy Commission) in the 1940s and 50s often use the words 'informed consent' and 'voluntary consent', and sometimes use language directly adopted from the Nuremberg Code.[2] Some local funding agencies had adopted consent requirements on their own, without specific Federal communications, which goes to show that the universal and traditional nature of consent requirements was understood by many as being applicable to America's biomedical research. (ACHRE 1995a, p. 95) ACHRE also documented that by the late 1940s, the American Medical Association had repeatedly published its own code of ethics for research on human subjects, and this code called for "voluntary consent" of the research subject (ACHRE 1995a p. 135; Ethics, 1948). This code had in fact been read in testimony at the Nuremberg Medical Trials (Faden and Beauchamp, 1986; Grodin, 1992).

Had this information been available to the Task Force, I believe it would have significantly changed our understanding of functional ethical standards in the 1940s and 50s. It now seems clear that the major requirements of the Nuremberg Code were disseminated to some individuals or agencies by the U.S. government at that time.

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[2] Article 1 of the Nuremberg Code states: "The voluntary consent of the human subject is absolutely essential." Article 1 goes on to require that the subject be informed of the nature, purpose and hazards of the experiment; that the duty for ascertaining the "quality of the consent" rests on "each individual who initiates, directs or engages in the experiment" (i.e., no researcher can pass on the responsibility for obtaining consent to someone else); and that consent must be obtained "without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion." (ACHRE 1995a, p. 103)

For government agency memos on consent requirements see ACHRE 1995a, chapter 1.

However, what is also clear is that this information was not uniformly disseminated or enforced—specifically, in research proposals, funding contracts, or local institutional policies. Until the 1970s many local institutional policies did not comply with the Nuremberg Code and legally did not have to. (ACHRE 1995a, ch. 3)

Issues of Consent

Three types of consent were sought, and in some experiments documented as having been in some manner obtained, by the researchers at Fernald. One was outreach by letter to parents or guardians. The second was consent granted by the Superintendent for those boys who were wards of the state and under his guardianship. The third was "voluntary participation" by the boys themselves.

A letter sent to parents in 1949 by the superintendent of Fernald describes the study as follows: "We are very much interested in the various aspects of nutrition, particularly how the body absorbs various cereals, iron and vitamins. We are considering the selection of a group of our brighter patients [...] to receive a special diet rich in the above-mentioned substances for a period of time. It will be necessary to make some blood tests at stated intervals, similar to those to which our patients are already accustomed, and which will cause no discomfort or change in their physical condition other than possibly improvement." (Farrell, 1949) No mention of radiation is made in this letter.

Another letter addressed to parents, written by the medical director of Fernald, Dr. Benda, gives a vague description of the study, again making no mention of radiation, and concludes: "if you have not expressed any objections we will assume that your son may participate." (Benda, 1953a) In this case, lack of a negative reply was interpreted as consent.

Sometimes the parents were led to believe the experiment would provide direct benefit to their children. For example, a letter from Benda states: "The tests are made for improving the nutrition of our children," and ends with a promise to "help them more efficiently than before." (Benda, 1953b). The sad truth is that in comparison to their peers in the institution, this was true, because of the controlled and nutritionally-balanced meals provided to the subjects.

Attempts to obtain parental consent are documented only for the calcium studies. For the iron studies we have no records to confirm or deny attempts to get consent from parents. For the thyroid studies, at Fernald the Task Force found one letter from Benda to parents that actually *does* state the child would drink a small dose of radioactive iodine and sit in front of a Geiger counter for a half hour (Task Force, 1994). This letter suggests there was no fixed policy of cover-up, but rather, an inconsistent and paternalistic attitude of control over information. The researchers were allowed to decide for themselves whether and to what extent to inform the parents, often looking for the most rapid and effective way of obtaining consent.

From the consent forms that have been found, as well as the lists of names documenting which parents replied, and some actual notes sent back to the institution (Fernald records, 1953; Kelly, 1953), we must infer that the researchers did themselves feel the need, or had the directive, to obtain some type of consent first from the children themselves, and then from the parents (using the "consent" of the child to alleviate the parents' potential concern that the child would object).

Quality of life at Fernald Was the consent of the Fernald children 'voluntary'? To answer this question, we must first examine the context of life at Fernald. What type of facility was Fernald? Many residents were there because physicians or other experts had advised their parents that institutionalization in a state school was the only solution to their medical or social problems. Until the 1970s (and a class action lawsuit), buildings were dirty and in severe disrepair, staff shortages were constant, brutality was often the norm, and there were few if any witnesses or advocates available to safeguard the interests of the residents. (Task Force, 1994)

The following testimony from the parent of a former Fernald resident gives a picture of daily life at Fernald: "The first Sunday of each month was the only visiting time allowed. When I arrived, I was not allowed beyond the foyer. [...] On visiting, I occasionally got a glimpse of the day room. It was a large, bare room with a cement-like floor. In the middle of the room there was a circular grating where urine and feces were hosed down. Needless to say, the little girls wore no panties. This room had no chairs, the children sat or laid down on the cold flooring. Most of the children laid on the floor because they were given Valium two and three times a day." The same parent also recalls: "I saw roaches, red ants and mice darting in and out to pick up a few crumbs left on the floor. My daughter was delighted with the mice." (Task Force, 1994, p. 38)

One victim's relative states that his cousin had all her teeth extracted by a Fernald dentist, "so she would not be bothered with tooth decay and cavities." The parent of another victim states: "I was in and out of all the buildings and I remember what they were like. 'Horrible' is a tame word to describe them." (Task Force, 1994, p. 38–48)

Special privileges for participation Special privileges were offered as a reward for participating in the radiation experiments. These favors were more than enticing to children trapped in such a dreadful environment. The experiments allowed the subjects to participate in a 'Science Club' whose members were deemed the 'brightest students' and were eligible for outings offgrounds and dinner parties at MIT (Harris, 1953b). A letter to Benda from Dr. Harris, the director of MIT's Nutritional Biochemical Laboratories, states: "We need to round up about seventeen subjects if we hope to use fifteen in an experiment. If there is anything I can do to help in this please let me know. For instance, it occurs to me we have neglected the Fernald Science Club angle of our work and should line up a baseball game for the boys." (Harris, 1953a) Harris also writes, "It seems to me that the three subjects who objected to being included in the study can be induced to change their minds." (Harris, 1953a)

Dr. Benda seems to have taken this advice: in a letter to parents dated a month later he writes, "Your son has agreed to volunteer because the boys who belong to this Science Club have many additional privileges. They get a quart of milk daily during this time, and are taken to a baseball game, to the beach and to some outside dinners, and they enjoy it greatly." (Benda, 1953a)

It is clear that such opportunities would be almost impossible for most any Fernald resident to refuse. One former member goes so far as to state that during his time at Fernald, his membership in the 'Science Club' was "the highpoint of my life", and made other children jealous of him.(Personal communication)

It was communicated to me by some of the researchers that they felt a true affection for and friendship with many of the boys involved. They wanted the boys to have the special recognition and gifts. I believed the sincerity of that affection as expressed to me. But in the context of institutional life at that time, even honest affection by some of the researchers would create a desire in the boys to do anything just to spend time with someone who would give them this type of affection and tangible reinforcement.

Nonetheless, some children resisted participation, and the researchers attempted to overcome this resistance. Testimony before the ACHRE committee documents a case where two boys were "ostracized and condemned" by Fernald officials for not participating in the Science Club. (ACHRE, 1995b)

Differential Treatment of Subjects: Experimental Groups Chosen Based on Social Hierarchy, not Research Criteria

"It is no accident that the students at the Fernald School were fed radioactive iron and not the students at MIT"

—Congressman Edward Markey,
in testimony before the Subcommittee on Energy and Power.
(Markey, 1994)

The decision to use institutionalized children as experimental subjects appeared to me as clearly influenced by a tendency by society to dehumanize marginal people. For example, the AEC restricted the use of 'normal children' to one experiment only—while for mentally impaired children they made no such restriction (Lough, 1949c).

The researchers identified the following two criteria as reasons why Fernald children were selected: (1) Previous diet of the subjects had to be the same; (2) Convenient distance to MIT, where analysis of blood samples could be done (Task Force, 1994; Harris, 1945).

While the children at Fernald and Wrentham met these criteria, students at MIT would have met them as well. In fact, it would have been easier to use MIT students: not only did they fit the criteria of proximity to MIT much better than Fernald students, but they ate in a common cafeteria, and their intellectual development and successful socialization would have been helpful to their understanding of the importance of following the research protocol, for instance eating the same diet and details of urine and feces specimen collection.

It is my belief that the primary reason why MIT students were not chosen as subjects is simply this: most were economically privileged and all were members of an esteemed intellectual elite. It was a perceived social status, not realistic logic, that determined the selection of subjects. It was shared with me by persons who had been workers at Fernald since the time of the experiments that the medical community and teaching universities referred to Fernald and its inhabitants as "the zoo". Here was a contained environment with a diversity of medical conditions and a population of people who were not seen as otherwise valuable or deserving of concern. In other words, a perfect pool of applicants for biomedical research.

Management of the Experiments

The researchers, due either to a miscalculation or an intentional decision, administered a dosage greater than the maximum authorized dose of 1.0 microcuries in the calcium experiments. Letters circulated between the AEC, Benda, and a physics professor at MIT concerning the allowable dosage for each subject. In these letters, Benda was explicitly reminded that one microcurie was the maximum allowable dose (Lough, 1949a; 1949b; 1949c; Benda, 1949). One of the most fundamental aspects of research is controlling the dosage. If this overdose was a miscalculation, it was scientifically negligent. If it was intentional, the researchers knowingly violated their research protocol.

Neither the researchers nor the facility staff entered any information into the children's permanent medical records. This omission was not unique (and, in fact, appears to have been the norm due to a total lack of protective policy or law at the time), but its effect over the years has been to prevent anyone close to the children, such as their guardians or family doctors, from finding out about the experiments. It has also made a retroactive identification of the victims difficult and in some cases impossible. Had the dosimetry indicated that the victims bore significant health risks, large number of people would have been inaccessible for follow-up and preventive measures.

PART 4: RECOMMENDATIONS FOR CONSIDERATION AND CHANGE TO ASSURE OPTIMAL PROTECTION FOR SUBJECTS OF RESEARCH IN THE 21ST CENTURY

1. Record Keeping and Storage

The extensive records kept by Dr. Benda, and the sentimental value he attached to them (preserving records most others would have long since destroyed), provided crucial evidence for the investigation. Accurate and complete record-keeping is important for quality research, as well as for remedying any unforeseen consequences of the research. Research subjects, their advocates, and lineal descendants must have access to an accurate record of what was done, why it was done, and to whom it was done. If accurate records from past research are not available, it is difficult to trust present research. Some of the outrage experienced by the victims and their families could have been minimized if accurate records had been more easily accessible. This would have allowed the Task Force to answer their questions in a timely manner based on verifiable records which concerned persons could themselves inspect. Given the lack of proper record keeping, many of the family members and advocates now assume that other secret studies were done and remain to be discovered.

Within the original report, the following recommendations were made to the Department of Mental Retardation (DMR). These requirements should be met by every funding source and every individual, group or institution involved in research:

a. Any application for research to be done by or at a given facility should have a space on the application that requires identification of the person(s) responsible for record-keeping and of the location where the records will be permanently stored;
b. A percentage of the research funds should be earmarked for proper storage and professional cataloging of the records;
c. Any human subjects in the research should be noted in the permanent confidential record by name, current address and social security number along with exact dosages and materials administered or exposed to;
d. A copy of the protocol and specifics of the study should be placed in the person's medical record. A copy should be sent to his/her attending physician (with the subject's permission) and a copy given to the person or his/ her legal guardian.

In addition to these original recommendations, I would like to make the following additional recommendations:

e. All research facilities, public and private, should review and list existing archival materials and collaborate with an archival or historical society to determine the most appropriate location for their storage;
f. Current research that has not yet prepared for record-keeping and archival needs should do so and add an addendum to the records to assure that a proper paper trail exists;

g. Persons who are responsible for record-keeping should consult with or be trained by professional archivists to ensure that ignorance does not prevent the accurate assessment and placement of key files;
h. Colleges, universities, hospitals and all other research facilities should have clear written standards detailing how records should be kept and which records are deemed personal or professional. This will prevent individuals from deciding unilaterally what papers can be removed from the institution's records;
i. All researchers should recognize the vital link their personal copies of records provide in the chain of investigation, and make plans to offer them eventually to an appropriate archival setting.

2. Ethical Issues in Biomedical Research

The Fernald and Wrentham experiments raise important ethical issues related to the use of captive groups and/or persons with cognitive impairment in biomedical research, particularly non-therapeutic research.

The obvious question raised is "Can consent given by institutionalized persons or by guardians for legally incompetent individuals be considered ethically valid?" Many argue that even therapeutic research should be off-limits to this vulnerable population. However, the "right to risk" is a major point of discussion in the disability rights movement. Citizens, policy-makers, and researchers must confront this issue and the question it raises: "Should people deemed 'legally incompetent' be denied the opportunity to engage in non-therapeutic research if they so desire, or if their legal guardian feels it would be desirable to them?"

The choice to deny legally incompetent individuals the ability to participate in research would also deny the benefits of new and untested technology to those whose minds or bodies are deemed 'abnormal' by current standards.

One way to help in this decision making would be to create a distinction between different types of guardians of legally incompetent individuals: family members, or people who know and love the individual, will be better able to decide than administratively appointed officials, for example. Family members or people who provide the actual loving daily care for that person (for instance a professional caretaker who has developed a true and loving relationship with that person) can make a decision that best reflects all that they know and see in a person's life and spirit, including a desire to participate in research—even if this desire is difficult for the person to express due to cognitive or communicative impairments.

The choices should not be based solely on whether the individual is able to make an informed decision, but also on the risks and intrusiveness of the research itself. The legal standard currently in use for research on children can provide guidance here, but will have to be adapted to the unique situation of adults with cognitive impairments.

The issue is further complicated if one considers the relative merits of therapeutic and non-therapeutic research. Since there is theoretically a potential gain for the participant in therapeutic research, greater latitude should be given to the institutionalized or legally incompetent individual to permit participation. Obviously, analysis is required in such situations to ensure that the benefits warrant the risks. An important focus in this analysis must be the potential benefit of the research, the medical condition of the participant, and what other treatment options are available.

Today, we rely on Institutional Review Boards (IRBs) to review and authorize most human research in order to ensure that no one person has the sole authority to approve such research. This review system should be revised. Within the current system, there is still insufficient involvement of civilian groups in the review process. Mentally impaired individuals themselves (a number of whom currently serve as nationally or locally recognized and respected advocates within disability rights) and/or relatives of and advocates for mentally impaired individuals must also be included on these IRBs.

CONCLUSION

The Fernald and Wrentham experiments met and in some areas even exceeded contemporary institutional practices and standards. What can we learn from this research that will shape our own present practices? Are we so naive or egotistical as to believe that we have reached the pinnacle of ethical and scientific knowledge, that our present protocols are truly ethical vs simply technically correct?

We are currently facing demanding ethical issues such as fetal tissue implants, human genome discoveries and therapies, euthanasia rights or protections and AIDS immunization that did not exist when the foundations of current standards were established. These issues stretch our ethical knowledge and boundaries. They also pose large and potentially serious consequences for haste and intemperance. As a result, these issues require extensive rethinking and reconsideration of our current research practices and definitions. Yet consumer groups are currently demanding a more streamlined process to get access to the earliest and newest protocols still in development, especially with issues such as HIV/AIDS research.

I personally recommend a more interactive standard of informed consent. A few stapled pages of medical terms and a list of potential side effects have about as much impact on the average person as warnings on cigarette packs, diet soda cans or seat belt buzzers in cars. If a person is in severe pain, bleeding, facing terminal illness, or waiting beside a loved one facing imminent death, a signature on a piece of paper does not prove 'informed consent'. It simply makes lawyers able to say consent was gotten. Informed consent must become a living document and process, evolving and remaining open to change throughout a research or therapeutic procedure. Once my pain is abated, once I first experience a side effect of treatment, or once I learn in concrete form what the risks of the procedure will be—only then can I have sufficient knowledge to further define my informed consent. On that first day I can give initial consent; at the middle I can give continued and better informed consent; but only at the end can I give informed assent.

We must be aware that in 40 to 50 years there may be a task force called to account for what was done by any one of us today. Understanding that someone successfully met the standards of their day does not justify their actions or prevent retrospective ethical judgments. Rather, it allows us to understand the fallibility of any current standard if it is held as a rigid defense. We must not simply condemn or forgive the past: we must learn from it.

This is my challenge to my colleagues in the field of bioethics today. I offer that no standards are anything more or less than "the standard of the day." They must be examined and updated on an ongoing basis. And the time to do that next major revision is now.

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